

THE CAMBRIDGE STATISTICS DISCUSSION GROUP

Thursday 6th April 2000 7:15 for 7:45

Honor Fell Room,
Strangeways Research Laboratory,
Worts Causeway, Cambridge

Drug Regulation: What do statisticians contribute?

Jim Slattery

Medicines Control Agency,
London

Abstract: The Medicines Control Agency (MCA) has employed full time statisticians for only a few years. There are now four statisticians involved in assessing the strength of support provided by clinical trials for decisions to grant marketing authorisations and one involved in assessing drug safety issues arising with products already on the market. We also have one statistician or epidemiologist at each meeting of our main advisory committee, the CSM.

These figures contrast with about 50 doctors and rather more scientific and pre-clinical assessors employed by the MCA. A similar imbalance in numbers is carried over to the CSM.

How do statisticians fare as a small but vocal minority in terms of our contribution to drug regulation? Do we punch above our weight because of the ubiquity of statistical arguments in drug development or are we simply unable to communicate the more complex arguments and out-voted on committees?

The speaker will give a description of what drug regulators do both within our national agency, the MCA, and in collaboration with the European Medicines Evaluation Agency. He will explain what the UK drug regulation statisticians do and give a personal view of their contribution.

Speaker: Jim Slattery spent about nine years as a statistician in the Neurosciences Trials Unit of Edinburgh University. He has been at the Medicines Control Agency for three years; two in Licensing Division and one in Post Licensing.

Directions: Head away from Cambridge city centre along the Hills Road. About 200 yards after the hospital roundabout a road (signposted 'Fulbourn 3') forks off to the left – this is Wort's Causeway. Strangeways Research Laboratory is the first building on the right on Wort's Causeway. There is car parking both at the front and the rear of the building. Access to the building may be difficult after 7:45.

Next Meetings: (Please note change of the May speaker)

4th May – Tish Ornstein (Department of Psychiatry) on 'Assessing cognitive functioning in brain damaged patients'.

5th October – Tim Cole (Institute of Child Health, London) on 'Sympercents: A simplified presentation of natural log transformed data'.

Supper: Some members eat regularly in the University Centre before each meeting at 6-15. Feel free to join them.

Subscriptions: of 4 pounds per member are now due for the 1999-2000 session. Cheques should be made payable to Robert Milroy and may be posted to the secretary at the address below.

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